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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,435	09/06/2000	Akiko Itai	195832US	9728

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/656,435

Applicant(s)
Itai et al.

Examiner
Michael Borin

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1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Amendment filed 7/31/02 is acknowledged. Claims 6-11 are amended. Claims 6-11 are pending.

2. As was stated in the previous Office action, in view of plurality of issues under 35 USC112 paragraph, only such issues are addressed at this point. Upon clarification of the issues addressed in the rejections under 112, first and second paragraphs, below, a potential restriction requirement, rejections over prior art (previously and newly applied), and respective applicant's arguments, will be addressed.

It is noted that applicant did not address rejections of record individually; rather, applicant submits that amendments to the claim obviate the rejections. This is not deemed convincing. Rejections of record are reiterated below, along with additional rejections necessitated by amendments.

Claim Rejections - 35 USC § 112, second paragraph.

3. Claim 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. The rejection is applied for the following reasons:

- A. The new language in amended claims is not clear: In the step of "inputting", the dummy atoms seem to refer to atoms of ligand mimicking the ligand and being tested for interaction with biopolymer; however, in the next step of "covering" or "selecting", the dummy atoms are addressed as interacting with ligand, not biopolymer.
- B. Claims 7,9: The term "selecting" remains vague and indefinite. The term is not defined either by the claim or in the specification, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

Applicant argues that "selecting" addresses "stable" docking structures; however, the claims is drawn to selecting "possible" docking structures, and the criteria for such selection are not clear. In fact, the claims as now amended, relate the dummy atoms (derived from ligand) with the ligand itself, not the biopolymer.

- C. Claims 6,8: The term "covering" remains vague and indefinite. The term is not defined either by the claim or in the specification. Applicant submits that the meaning of the claims is for the program "to look" at all permutations of docking structures; however, it does not reflect a particular positive method step; the meaning of "looking" is not clear, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention. Further, applicant contends that the program

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looks at all permutations of docking structures "given the specified dummy atoms". However, no relation of "covering" step to dummy atoms is claimed. In fact, the claims as now amended, relate the dummy atoms (derived from ligand) with the ligand itself, not the biopolymer.

D. Claims 10,11 are vague and indefinite because the claims are drawn to estimating interaction between a biopolymer and a ligand, and the only method step is drawn to matching distances between dummy atoms and atoms of ligand; there is no nexus to biopolymer-ligand interaction.

E. Claims 8,9,11: The term "specifically interact with functional groups " is vague and indefinite. In which regard dummy atoms "specifically interact" with the functional groups in the biopolymer. The term is not defined by the claims or specification, the specification does not provide a standard for ascertaining the requisite "specific interaction", and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

F. Claims 6-9: The language "inputting ...atomic element, bond type or covalent bond and three dimensional coordinates for each atom of the ligand" is not clear. Does it mean inputting, first, atomic element, bond type or covalent bond, and, second, the three dimensional coordinates for each atom of the ligand? Or it is that for each atom of the ligand the parameters of atomic element, bond-type or covalent bond, three

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dimensional coordinates are entered? If the former is correct, what is an "atomic element". Also, how bond type is different from covalent bond (which is a specific type of a bond)?

G. Claims 6-11: The term "stable" in regard to determining docking structures is not clear. The method steps are limited to matching of distances, there are no steps to determine any "stability", therefore, the meaning of this term (conformational, energetic, etc.) is not clear.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8,9,11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 8,9,11 introduce new matter as they recite that dummy atoms are being preset at positions that "specifically interact with functional groups" in the biopolymer. There is no

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disclosure in the specification on the meaning and scope of the newly claimed term and there is no guidance on how to practice the method(s) as now claimed.

5. Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 6,8 and 7,9 (or rather now canceled claims 4,5) introduce new matter as they recite steps of "covering" and "selecting" of docking structures, respectively. There is no disclosure in the specification on the meaning and scope of the newly claimed terms and there is no guidance on how to practice the method(s) as now claimed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 7, 2002

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

